

**GOOD SENSE SEVERE DAYTIME COLD AND FLU- acetaminophen,
dextromethorphan hbr, guaifenesin, phenylephrine hcl solution
L. Perrigo Company**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Perrigo Severe Day Time Cold & Flu Drug Facts

Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- sinus congestion and pressure
- nasal congestion
- minor aches and pains
- headache
- reduces swelling of nasal passages
- sore throat
- promotes nasal and/or sinus drainage
- fever
- cough due to minor throat and bronchial irritation
- temporarily restores freer breathing through the nose
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **take only as directed - see Overdose warning**
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

| | |
|---------------------------------|-------------------|
| adults & children 12 yrs & over | 30 mL every 4 hrs |
| children 6 to under 12 yrs | 15 mL every 4 hrs |
| children 4 to under 6 yrs | ask a doctor |
| children under 4 yrs | do not use |

Other information

- **each 15 mL contains:** sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

GOODSENSE®

Maximum Strength Relief

Non-Drowsy

Pain Reliever, Fever Reducer

Nasal Decongestant

Cough Suppressant, Expectorant

Severe DayTime Cold & Flu

Acetaminophen

Dextromethorphan HBr

Guaifenesin

Phenylephrine HCl

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Chest Congestion • Cough
- Nasal/Sinus Congestion & Sinus Pressure

Compare to active ingredients of Vicks® DayQuil® Severe

8 FL OZ (237 mL)

Alcohol Free

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Gluten Free

Distributed By

Perrigo®

Allegan, MI 49010



CODE AREA
• no varnish • no color

: 60334 C2 F4

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

GOODSENSE®

NDC 0113-0603-34

Maximum Strength Relief

Non-Drowsy Severe Pain Reliever, Fever Reducer
Nasal Decongestant
Cough Suppressant, Expectorant

DayTime

Cold & Flu

Acetaminophen
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| Dextromethorphan HBr 10 mg..... | Cough suppressant |
| Guaifenesin 200 mg..... | Expectorant |
| Phenylephrine HCl 5 mg..... | Nasal decongestant |

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PEEL BACK AT CORNER FOR MORE INFORMATION →

ADHESIVE AREA NO COPY

Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredients butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions or comments? 1-800-719-9260

GOOD SENSE SEVERE DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0113-0603 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg in 15 mL |

| | | |
|---|----------------------------------|--------------------|
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 15 mL |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg in 15 mL |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1VS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg in 15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SUCROSE (UNII: C151H8M554) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|----------------|---------------------|--|
| Color | ORANGE (clear) | Score | |
| Shape | | Size | |
| Flavor | FRUIT, MENTHOL | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0113-0603-34 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 11/19/2013 | |
| 2 | NDC:0113-0603-40 | 354 mL in 1 BOTTLE; Type 0: Not a Combination Product | 11/19/2013 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 11/19/2013 | |

Labeler - L. Perrigo Company (006013346)